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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/596,362 | 06/17/2000 | Gregory Steiner | | 1986 |

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Gregory Gene Steiner
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EXAMINER

WARE, TODD

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 10/22/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/596,362

Applicant(s)

STEINER, GREGORY

Examiner

Todd D Ware

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt of assignment of power of attorney, and amendment both filed 6-24-02, and amendment filed 7-10-02. Claims 7-9 have been canceled and new claims 10-16 have been added.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6-24-02 and 7-10-02 have been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Recitation of "to taste similar" in line 1 of claims 13-16 is indefinite since it is not clear what applicant intends to cover by this recitation. No criteria for ascertaining the taste of the beverage nor the steps for achieving this taste are provided.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Holzer (983,998; hereafter '998).

6. '998 discloses beer having kava. Craving for alcohol is reduced/treated by administration of the beer.

7. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kryspine (1974).

8. Kryspine discloses reduction of symptoms of chronic alcohol abstinence syndrome with administration of kava to alcoholic patients in alcohol withdrawal. Craving for alcohol would necessarily be reduced as the same compound is being administered to alcoholic patients in alcohol withdrawal. Furthermore, reduction in the symptoms associated with alcohol withdrawal would reduce craving for alcohol since patients would not desire alcohol to combat the symptoms of alcohol withdrawal.

Claim Rejections - 35 USC § 103

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kryspine (1974).

12. Kryspine teaches reduction of symptoms of chronic alcohol abstinence syndrome with administration of kava to alcoholic patients in alcohol withdrawal. Kryspine does not specifically teach that alcohol craving is reduced, however it would have been obvious to one skilled in the art at the time of the invention to reduce alcohol craving with kava since Kryspine teaches reduction in the symptoms associated with alcohol withdrawal which would reduce craving for alcohol since patients would not desire alcohol to combat the symptoms of alcohol withdrawal. The motivation for reducing the craving is to treat alcoholism.

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13. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kryspine (1974) in combination with Gillmer (1973) and further in combination with Cody (6,045,825; hereafter '825).

14. Kryspine is relied upon for all that it teaches as stated previously. Kryspine does not teach administration of kava by means of transdermal patches, liquid beverages or tablets.

15. Gillmer is relied upon for teaching that treatment of alcohol withdrawal reduces anxiety in alcohol-dependent individuals. Gillmer does not teach administration of kava by means of transdermal patches, liquid beverages or tablets.

16. '825 is relied upon for teaching that kava has anxiolytic properties and administration of kava in transdermal patches, liquid beverages, tablets and capsules.

17. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the references and administer kava by means of transdermal patches, liquid beverages, tablets and capsules to treat alcohol craving since one would not crave alcohol to reduce the anxiety associated with alcohol withdrawal.

18. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kryspine (1974) in combination with Gillmer (1973) in combination with Cody (6,045,825; hereafter '825) and further in combination and further in combination with Lemert (1976).

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19. Kryspine, Gillmer, and '825 are relied upon for all that they teach as stated previously. The references are not sufficient to overcome the mode of administration with liquid beverages.
20. Kryspine is relied upon for all that it teaches as stated previously. Kryspine does not teach administration of kava by means of transdermal patches, liquid beverages or tablets.
21. Gillmer is relied upon for teaching that treatment of alcohol withdrawal reduces anxiety in alcohol-dependent individuals. Gillmer does not teach administration of kava by means of transdermal patches, liquid beverages or tablets.
22. Lemert is relied upon for teaching that kava has anxiolytic properties and administration of kava in liquid beverages.
23. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the references and administer kava by means of liquid beverages to treat alcohol craving since one would not crave alcohol to reduce the anxiety associated with alcohol withdrawal.
24. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kryspine (1974) in combination with Gillmer (1973) in combination with Cody (6,045,825; hereafter '825) and further in combination with Hinton et al (6,174,542; hereafter '542).
25. Kryspine, Gillmer, and '825 are relied upon for all that they teach as stated previously. The references do not equate the modes for administration with gum.

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26. '542 is relied upon for teaching equivalence of gum with liquid beverages, tablets and capsules.

27. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the references and administer kava by means of gum to treat alcohol craving since one would not crave alcohol to reduce the anxiety associated with alcohol withdrawal.

28. Claims 10-11, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kryspine (1974) in combination with Lemert (1976) and further in combination with Schur (4,661,355; hereafter '355).

29. Kryspine is relied upon for all that it teaches as stated previously. Kryspine does not teach administration in a liquid beverage.

30. Lemert teaches administration of kava in liquid beverages.

31. '355 is relied upon for teaching liquid beverages that are alcohol-free beer and wine beverages.

32. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the references to administer the kava in an alcohol-free beer or wine beverage with the motivation to treat alcohol craving through reduction in alcohol withdrawal symptoms where the beverage has the taste of beer or wine.

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33. Claims 12-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kryspine (1974) in combination with Lemert (1976) and further in combination with Rohman (4,990,350; hereafter '350).

34. Kryspine is relied upon for all that it teaches as stated previously. Kryspine does not teach administration in a liquid beverage.

35. Lemert teaches administration of kava in liquid beverages.

36. '350 is relied upon for teaching liquid beverages that are reduced alcohol spirit beverages.

37. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the references to administer the kava in a reduced alcohol spirit beverage with the motivation to treat alcohol craving through reduction in alcohol withdrawal symptoms where the beverage has the taste of distilled spirits.

Response to Amendment

38. The Declaration filed on 7-10-02 under 37 CFR 1.131 has been considered but is ineffective to overcome the Cody (6,045,825; hereafter '825) or Hinton et al (6,174,542; hereafter '542) references.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the these references. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be

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comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

39. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the references of paragraph 38. The declaration describes conception of the idea of treating alcohol craving, but does not provide support for the means of instant claims 3-5.


Conclusion

40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
October 21, 2002


THURMAN K. PAGE
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